

UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

INTERNATIONAL DAIRY FOODS
ASSOCIATION,

Case No. 2:08-CV-628
consolidated with
2:08-CV-629

and

JUDGE GRAHAM
MAGISTRATE JUDGE KING

ORGANIC TRADE ASSOCIATION,

Plaintiffs,

v.

ROBERT J. BOGGS, Director,
Ohio Department of
Agriculture,

Defendant.

OPINION AND ORDER

I. INTRODUCTION

Plaintiffs, two food associations whose members are engaged in the processing of dairy products, seek a declaratory judgment and preliminary and permanent injunction to prevent the Director of the Ohio Department of Agriculture ("ODA") from enforcing Ohio Administrative Code provision 901:11-8-01, which regulates the labeling of dairy products in Ohio. The matter is before the court for decision on all parties' motions for summary judgment.¹

¹Two briefs of Amici Curiae, one in support of plaintiffs and one in support of defendant, were also filed and considered.

II. STATEMENT OF FACTS

In 1993, the United States Food and Drug Administration ("FDA") approved the use of the hormone recombinant bovine somatotropin, or rbST, in dairy cows. The hormone is also known as recombinant bovine growth hormone, or rbGH. When used in dairy cows, rbST combines with naturally occurring bovine growth hormone, or bGH, to increase cows' milk production by up to ten percent. The FDA determined that the use of rbST is safe, that there is "no significant difference between milk from treated and untreated cows . . ." and "there is currently no way to differentiate analytically between naturally occurring bST and recombinant bST in milk, nor are there any measurable compositional differences between milk from cows that receive supplemental bST and milk from cows that do not." 59 Fed. Reg. 6279, 6280.

Despite the FDA finding, consumers, dairy producers and retailers continue to have differing opinions about the use of rbST. Due to increased demand for products from cows not treated with rbST, some dairy processors have begun to label their products with statements such as "rbST free" or "artificial hormone free." Dairy producers that use rbST have objected to these labels, arguing that these phrases are misleading because, despite FDA findings to the contrary, they imply that milk from cows supplemented with rbST is different from or inferior to milk from cows not supplemented with rbST.

On February 10, 1994 the FDA published interim guidance on the labeling of milk and milk products from cows that have not been treated with rbST. 59 Fed. Reg. 6279. The FDA guidance

provides that food companies that do not use milk from cows supplemented with rbST can voluntarily inform consumers of that fact in their product labels, provided that such statements are truthful and not misleading. The FDA determined that the term "rbST free" "may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced. Instead, the concept would be better formulated as 'from cows not treated with rbST' or in other similar ways." 59 Fed. Reg. 6279. Thus, the FDA guidance suggests that it is preferable to discuss how the milk is produced, rather than the composition of the milk.

The FDA also found that even such a statement, which asserts that rbST has not been used in milk production, has the potential to be misunderstood by consumers without proper context because such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. According to the FDA, "[s]uch an implication would be false and misleading." Id. Thus, the FDA guidance states that these misleading implications can be best avoided by use of accompanying contextual information, such as accompanying the production claim "from cows not treated with rbST" with a disclaimer such as "no significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows." Id.

The FDA noted that given the traditional role of the States in overseeing milk production, it intended to rely primarily on the States to ensure that rbST labeling claims were truthful and not misleading. Because there is no way to differentiate

analytically between naturally occurring bST and synthetic rbST in milk, the FDA found that to ensure claims that milk comes from untreated cows are valid, States could require firms using such claims establish a plan and maintain records to substantiate the claims and make those records available for inspection.

In a letter dated July 27, 1994 from the FDA to the Director, Division of Milk Control for the State of New York, the FDA indicated that interim guidance was developed to "provide all states with the same starting point for their efforts in this area" and the intent was to "assure as much uniformity as possible among state regulations." IDFA App. 0003. However, the letter pointed out that the FDA guidance is not a regulation and therefore does not by itself legally bind states or manufacturers, but simply gives guidance to what the agency might determine is "truthful and not misleading" in accordance with the FDA's statute.

On February 7, 2008, Ohio Governor Ted Strickland issued Executive Order 2008-03S. The Order authorized ODA to immediately adopt a rule on what constitutes false and misleading labels on dairy products, require dairy producers who claim they do not use rbST to submit appropriate documentation for ODA review, and create labels consistent with the FDA's findings on rbST.

In response to this executive order, the Director solicited comments from consumers, producers, scientists and other interested parties. He convened a listening session to discuss dairy labeling, appointed an advisory committee on dairy labeling, conducted a public hearing to receive public comments on the emergency rule, made certain changes to the proposed rule

and submitted it to the Ohio Joint Committee on Agency Rule Review ("JCARR"). He then conducted a second public hearing for comments on the proposed rule and after revision, the Director sent the modified rule to JCARR for review. When arguing for the rule in front of JCARR, Director Boggs stated the rule does not try to favor the use of rbST in dairy production or to oppose it, but simply tries to provide the consumer with accurate information. IDFA App. II 583. The Director also obtained estimates from large, medium-sized, and small dairy processors of the anticipated costs they would incur in complying with the rule. The Director issued a final, revised version of the rule that was adopted on May 12, 2008 and became effective May 22, 2008. The final rule is published at Ohio Admin. Code 901:11-8-01.

The full text of the rule is as follows:

(A) Pursuant to sections 917.05 and 3715.60 of the Revised Code, dairy products will be deemed to be misbranded if they contain a statement which is false or misleading.

(B) A dairy label which contains a production claim that "this milk is from cows not supplemented with rbST" (or a substantially equivalent claim) may be considered misleading on the basis of such language, unless:

(1) The labeling entity has verified that the claim is accurate, and proper documents, including, but not limited to, producer signed affidavits, farm weight tickets and plant audit trails, to support the claim, are made readily available to ODA for inspection; and

(2) The label contains, in the same label panel, in exactly the same font, style, case, and color and at least half the size (but no smaller than seven point font) as the foregoing representation,

the following contiguous additional statement (or a substantially equivalent statement): "The FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows."

(C) Making claims regarding the composition of milk with respect to hormones, such as "No Hormones", "Hormone Free", "rbST Free", "rbGH Free", "No Artificial Hormones" and "bST Free", is false and misleading. ODA will not permit such statements on any dairy product labels.

(D) Statements may be considered to be false or misleading if they indicate the absence of a compound not permitted by the United States food and drug administration to be present in any dairy product, including, but not limited to antibiotics or pesticides. Except as otherwise provided in this rule, accurate production claims will not be deemed false or misleading.

(E) All dairy product labels must meet the requirements of this rule no later than one hundred twenty days after its effective date.

(F) The provisions of this rule shall not be construed to prohibit seals or marks referenced in and specifically authorized by a federal law or Ohio statute.

All parties to this case have filed motions for summary judgment which are now ripe for decision. Plaintiffs bring this case against Robert J. Boggs, the Director of the ODA ("Director"). Plaintiff International Dairy Foods Association ("IDFA") is a trade association whose members represent more than 85 percent of the milk, cultured products, cheese and frozen desserts produced in the United States. Plaintiff Organic Trade Association ("OTA") is a membership-based business association for the organic industry in North America. According to OTA's website, organic products are those produced

based on a system of farming that maintains and replenishes soil fertility without the use of toxic and persistent pesticides and fertilizers. Organically produced foods also must be produced without the use of antibiotics, synthetic hormones, genetic engineering and other excluded practices, sewage sludge, or irradiation. Cloning animals or using their products would be considered inconsistent with organic practices. Organic foods are minimally processed without artificial ingredients, preservatives, or irradiation to maintain the integrity of the food.²

Plaintiffs argue that the Ohio rule is unconstitutional because it infringes on their First Amendment right of free speech and violates the dormant Commerce Clause.³ OTA's motion also argues the rule is preempted by the Organic Foods Production Act (OFPA) and is void for vagueness. For the reasons discussed below in this opinion, this court grants in part and denies in part the Director's motion for summary judgment and denies the plaintiffs' motions for summary judgment.

III. DISCUSSION

A. Standard of Review

Under Fed. R. Civ. P. 56(c), summary judgment is proper "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a

²OTA.com, Quick Overview Organic Agriculture and Production, <http://www.ota.com/definition/quickoverview.html> (last visited April 1, 2009).

³IDFA has included in its complaint a Fourteenth Amendment Equal Protection claim, but no party has moved for summary judgment on that claim or argued they are entitled to a preliminary injunction on that claim and thus, it remains pending.

matter of law." See Daugherty v. Sajar Plastics, Inc., 544 F.3d 696, 702 (6th Cir. 2008); LaPointe v. United Autoworkers Local 600, 8 F.3d 376, 378 (6th Cir. 1993). The party that moves for summary judgment has the burden of showing that there are no genuine issues of material fact in the case at issue, LaPointe, 8 F.3d at 378, which may be accomplished by demonstrating that the nonmoving party lacks evidence to support an essential element of its case on which it would bear the burden of proof at trial. Walton v. Ford Motor Co., 424 F.3d 481, 485 (6th Cir. 2005); Barnhart v. Pickrel, Schaeffer & Ebeling Co., L.P.A., 12 F.3d 1382, 1389 (6th Cir. 1993). In response, the nonmoving party must present "significant probative evidence" to demonstrate that "there is [more than] some metaphysical doubt as to the material facts." Moore v. Philip Morris Cos., Inc., 8 F.3d 335, 340 (6th Cir. 1993). "[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine issue of material fact*." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986) (emphasis in original); see generally Booker v. Brown & Williamson Tobacco Co., Inc., 879 F.2d 1304, 1310 (6th Cir. 1989). Thus, "[o]nly disputed material facts, those 'that might affect the outcome of the suit under the governing law,' will preclude summary judgment." Daugherty, 544 F.3d at 702 (quoting Anderson, 477 U.S. at 248).

A district court considering a motion for summary judgment may not weigh evidence or make credibility determinations. Daugherty, 544 F.3d at 702; Adams v. Metiva, 31 F.3d 375, 379 (6th Cir. 1994). Rather, in reviewing a motion for summary judgment, a court must determine whether "the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a

matter of law." Anderson, 477 U.S. at 251-52. The evidence, all facts, and any inferences that may permissibly be drawn from the facts must be viewed in the light most favorable to the nonmoving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Eastman Kodak Co. v. Image Technical Servs., Inc., 504 U.S. 451, 456 (1992). However, "[t]he mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." Anderson, 477 U.S. at 252; see Dominguez v. Corr. Med. Servs., 555 F.3d 543, 549 (6th Cir. 2009).

B. First Amendment Freedom of Speech

The parties do not dispute the FDA's findings that there is "no significant difference between milk from treated and untreated cows . . ." and "there is currently no way to differentiate analytically between naturally occurring bST and recombinant bST in milk, nor are there any measurable compositional differences between milk from cows that receive supplemental bST and milk from cows that do not." 59 Fed. Reg. 6279, 6280. At the inception of this case, the court held a initial preliminary injunction conference with all parties. (See Transcript for case no. 2:08-cv-628, Doc. 19). The court inquired what evidence the parties intended to rely on in making their cases. In response, the Director indicated that he believed they may need an expert on the science behind rbST and why it has the clear potential to mislead consumers. In response, both plaintiffs assured the court that such testimony would likely not

be necessary.⁴ Plaintiffs do not attack or dispute the science behind the FDA findings in their motions for summary judgment. Thus, for purposes of this case, the FDA findings are not in dispute.

To resolve this case under the First Amendment protection for free speech, this court must apply First Amendment law to two separate parts of the Ohio rule⁵ - composition claims and production claims. "Composition" claims concern the content of the final dairy product itself and certain composition claims are subject to a prophylactic ban by the Ohio rule. Ohio Admin. Code § 901:11-8-01(C) and (D). "Production" claims concern the manner in which the milk was produced, including products given, or not given, to the dairy cows which produced the milk and, while permitted by the Ohio rule, are subject to certain restrictions such as accompanying the production claim with a disclaimer that must be in a specific location, font, style, case, color, and size. Ohio Admin. Code § 901:11-8-01 (B).

⁴At the conference, counsel for the Director indicated "I believe that there probably will be the need for at least one expert witness . . . to deal with some of the science issues related to rbST, what it means or doesn't mean in the production of milk and why, from a scientific standpoint, it has the clear potential to mislead consumers." (Case no. 2:08-cv-628, Doc. 19, p. 32). In response, Counsel for IDFA stated he thought the issues were largely legal and there may be some "factual red herrings about what the science is. We think that's irrelevant." (*Id.* at 33). Likewise, counsel for OTA stated "I don't think we are taking on the science issue directly as [the Director's counsel] seemed to indicate." (*Id.* at 34).

⁵First Amendment applies to the states through the Due Process Clause of the 14th amendment. Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 749 n.1 (1976).

1. The Prophylactic Ban On Certain Composition Claims

The Ohio rule bans certain composition claims, such as "rbST" free" and other similar terms. Both parties concede that the speech at issue here is commercial speech and under the First Amendment, commercial speech is entitled to protection that is somewhat less extensive than that afforded noncommercial speech. Zauderer v. Office of Disciplinary Counsel of Supreme Court, 471 U.S. 626, 637 (1985). "The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading . . ." Id. at 638. Misleading commercial speech may be prohibited entirely. Peel v. Att'y Registration & Disciplinary Comm'n, 496 U.S. 91, 100 (1990).

When evaluating a prophylactic ban, where commercial speech is *not* false, deceptive, or misleading it may be restricted only in the service of a substantial government interest and only through means that directly advance that state interest. Zauderer, 471 U.S. at 638. Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980) lays out a four-part analysis applied to commercial speech to determine whether a prophylactic ban violates the First Amendment. Step one of the test is to determine whether speech is false, deceptive, or misleading. Central Hudson, 447 U.S. at 566. If it is, the analysis ends at the first step and the speech is not entitled to First Amendment protection.

In order to ban terms as misleading, the Supreme Court has stated that the terms must be *either* 1) inherently misleading or 2) have been shown to be misleading based on a history of

deception. In re R. M. J., 455 U.S. 191, 202 (1982). Inherently misleading phrases are those "inherently likely to deceive" Id. Even if truthful, speech can still be misleading if its *implication* is misleading. In Zauderer, the Court found speech restrictions justified where an attorney advertised that all "fees" would be reimbursed but failed to mention that the client was responsible for costs. Zauderer, 471 U.S. at 652. The Court held that such an advertisement would suggest that employing the attorney would be entirely free of charge. Id. Given that members of the public are usually unaware of the technical meanings of terms such as "fees" and "costs" and that in ordinary usage, those terms might be perceived as interchangeable, the Court found the advertisement was deceptive and the possibility of deception was "self-evident." Id.⁶

Conversely, in Peel, the Court found that an implication was not sufficient to render a statement inherently misleading where that statement was "true and verifiable." Peel, 496 U.S. at 100. In Peel, a trial attorney sought to hold himself out as a "Certified Civil Trial Specialist" and the Illinois Supreme Court found that such a claim was inherently misleading because it implied the attorney's skills were superior to those not so designated. Id. at 101. The Supreme Court disagreed, stating that "[a] lawyer's certification by NBTA is a verifiable fact, as are the predicate requirements for that certification." Id. In Peel, the court noted that had the certification been issued by an

⁶In Zauderer, this implication was resolved with contextual language. As discussed below, contextual language will not resolve the misleading implication of the language at issue here.

organization that made no inquiry into the petitioner's fitness, or one that issued certificates indiscriminately for a price, the statement, even if true, could be misleading. Id. at 102.

In this case, the Director argues that the terms "rbST Free", "rbGH Free", and "No Artificial Hormones," are inherently misleading because they are not verifiable and because they imply that there is a compositional difference between milk so labeled and other milk not so labeled, which is untrue.⁷ The plaintiffs argue that the terms are only *potentially* misleading and that this potential can be resolved by using contextual language. Peel, 496 U.S. at 110.

The court agrees that the phrases "rbST Free", "rbGH Free", and "No Artificial Hormones" are inherently misleading. They are inherently likely to deceive because they all imply that the product is "free" of rbST or other hormones. In other words, they imply a compositional difference between those products that are produced with rbGH and those that are not. But in fact there is "no significant difference between milk from treated and untreated cows . . ." and "there is currently no way to differentiate analytically between naturally occurring bST and

⁷Plaintiffs argue that the Director did not have the purpose of preventing misleading information, but instead stated in a press release that the purpose was to give "balanced information" and in a separate letter to give "only the most accurate" information. IDFA App. 105, 438. The Director has attached an affidavit to his motion that specifically states that the rule is "intended to ensure that Ohio consumers receive truthful and non-misleading label information . . ." The fact that the Director did not use specific legal terminology in his prior statements is not determinative. Those statements were equivalent to the Director stating the aim of the rule was to prevent dissemination of misleading information.

recombinant bST in milk, nor are there any measurable compositional differences between milk from cows that receive supplemental bST and milk from cows that do not." 59 Fed. Reg. 6279, 6280. Thus, any implication that there is a difference between the two products is a misleading implication.

Plaintiffs argue that the terms "rbST Free", "No Artificial Hormones", and "rbGH Free" are not misleading because they can be verified based on farmer and processor production certifications because milk not produced with rbST could not possibly contain rbST. But such verification would not work to verify the composition claim, that the product is "free" of a particular substance, but instead would verify only an accurate production claim, that the product is not produced with rbST. Such an accurate production claim is expressly permitted by the rule. Even if milk labeled "rbST Free" does not contain rbST, the phrase is misleading because it implies that other products not so labeled do contain the hormone and are compositionally different.

Here, the situation is akin to the hypothetical described in Peel. 496 U.S. at 102. There the court said that a statement claiming that an attorney was certified by an organization would be misleading, even if true, if the organization made no inquiry into his fitness or issued certificates indiscriminately for a price because it would imply that the attorney had different or additional skills when in fact he did not. Id. Similarly, here, claims that a dairy product is "free" of a particular substance implies that the composition of the product is different than other products when in fact, the composition of that dairy

product is no different than any other dairy product on the shelves.

Plaintiffs argue that the terms banned by the Ohio rule are at most only *potentially* misleading and that potential can be resolved by simply requiring the use of contextual language. Id. at 109 (where information is only potentially misleading, there is a presumption favoring disclosure over concealment).

Plaintiffs' have offered a variety of contextual language that amounts to simply adding a production claim, such as "produced from cows not supplemented with rbST" alongside a term such as "rbST Free." But simply adding language that milk was produced from cows not treated with rbST does not cure the misleading nature of a term such as "rbST Free" because it still implies some compositional difference in the milk, regardless of how the milk is produced. Similarly, adding the "no significant difference . . ." language from the rule would also not serve to dispel any misleading implications. Adding such a statement would only serve to confuse a consumer because the label would contain contradictory information- it would say a product is "free" of rbST, but at the same time state that there is no rbST in other products, which defeats the purpose of making the claim in the first place.

In addition to the prophylactic ban on terms regarding the absence of hormones, the Ohio rule also places a prophylactic ban on terms that indicate the absence of a compound not permitted by the FDA to be present in any dairy product, including, but not limited to antibiotics or pesticides. Ohio Admin. Code 901:11-8-01(D). These statements, like composition claims

regarding hormones such as "rbST Free," are also inherently misleading because of their implication. These terms likewise imply a compositional difference between products so labeled and those not so labeled. These statements imply that other products have antibiotics or pesticides in them when they do not because such compounds are prohibited by the FDA.⁸

Finally, the Ohio rule bans terms such as "No Hormones", "bST free", or "Hormone Free." These phrases are false because all dairy products contain some natural hormones. Because the prophylactic ban at issue in the statute bans terms that are inherently misleading or false, those terms are not entitled to First Amendment protection and this court need not address the remaining Central Hudson factors.

2. Disclaimer Imposed on Production Claims

In addition to an outright prophylactic ban on certain terms, the Ohio rule also requires that production claims be accompanied by a disclaimer. Specifically, the Ohio rule requires that when a processor makes a production claim on its label, such as "this milk is from cows not supplemented with rbST,"⁹ that claim may be considered misleading unless the labeling entity has verified the claim is accurate with proper documentation and the label contains the statement: "The FDA has determined that no

⁸The parties do not dispute that dairy products are not permitted to have antibiotics or pesticides in them.

⁹Under the Ohio rule, substantially equivalent claims are also permitted.

significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows." Ohio Admin. Code § 901:11-8-01(B)(2). The disclaimer must be on the same label panel as, and contiguous to, the production claim and must be in exactly the same font, style, case, and color and at least half the size (but no smaller than seven point font).

Although the four part Central Hudson test is used to evaluate bans on speech, a more lenient approach is taken when evaluating a state's requirement that a disclosure be made. Zauderer, 471 U.S. at 650-651.¹⁰ Disclosure requirements, unlike prophylactic bans, do not attempt to prevent a speaker from conveying information to the public, but rather require them to provide more information than they might otherwise be inclined to present. Id. Because disclosure requirements are not as intrusive on First Amendment rights as are prohibitions, the Supreme Court has held that an advertiser's rights are adequately protected as long as disclosure requirements are "reasonably related to the State's interest in preventing deception of consumers." Id. at 651. To demonstrate that use of a disclaimer is an appropriately-tailored check against deception or confusion, the State must show that it seeks to prevent a harm that is "potentially real, not purely hypothetical." Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 146 (1994).

¹⁰This court finds the Second Circuit's reasoning in Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001) (holding the Central Hudson test was not applicable in disclosure cases) a more persuasive reading and application of Zauderer than the Eleventh Circuit's reasoning in Brogner v. Brooks, 284 F.3d 1204, 1214 (11th Cir. 2002) and Mason v. Fla. Bar, 208 F.3d 952, 958 (11th Cir. 2000).

However, disclosure requirements still implicate First Amendment rights, and thus, unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech. Zauderer, 471 U.S. at 651.

a. *Reasonably Related to State's Interest*

Here, the Director's interest in requiring the disclaimer is to prevent the dissemination of potentially misleading information. Just like the composition claims discussed above, the accurate production claim at issue here has a misleading implication because it implies that those processors that do use rbST have an inferior or unsafe product or that it is compositionally different. Therefore, in order to prevent consumer confusion, the "no significant difference..." disclaimer is reasonable.¹¹ See Zauderer, 471 U.S. at 651 (holding that warnings or disclaimers may be appropriately required in order to dissipate the possibility of consumer confusion or deception).

Plaintiffs argue that the rule is unjustified because the Director has not shown the deception is "potentially real, not purely hypothetical." Ibanez, 512 U.S. at 146-147. But the Director is not required to produce exhaustive evidence to justify its rule. As stated in Zauderer "when the possibility of

¹¹Plaintiffs' attempt to relate this case to Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996) is not persuasive. The Vermont regulation at issue in Amestoy had nothing to do with preventing consumer deception and was later limited to "cases in which a state disclosure requirement is supported by no interest other than the gratification of 'consumer curiosity.'" See Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 114 (2d Cir. 2001).

deception is as self-evident as it is in this case, we need not require the state to conduct a survey of the public before it may determine that the advertisement had a tendency to mislead." Zauderer, 471 U.S. at 652-653 (internal quotations omitted).

Plaintiffs argue that language from Ibanez effectively overrules this part of the Court's ruling in Zauderer so that the Director is required to provide evidence of actual deception. Plaintiffs read Ibanez too broadly. In Ibanez, the Florida board of accountancy issued a complaint against Ibanez, an attorney, charging her with violating the board's administrative regulations prohibiting false, deceptive, or misleading advertising because she appended the CFP designation (Certified Financial Planner) after her name, when such designation had not been approved by the board as a specialty designation. The Court held that, absent evidence of consumer confusion, there was no reason to believe that such a designation, if truthful, was misleading, particularly in light of Peel. The Court specifically stated that they expressed "no opinion whether, *in other situations* or on a different record, the Board's insistence on a disclaimer might serve as an appropriately tailored check against deception or confusion." Ibanez, 512 U.S. at 146 (emphasis added).

The Ohio Supreme Court also declined to read Ibanez as broadly as plaintiffs suggest. In In re Complaint Against Harper, the court stated that they did not read Ibanez "as requiring the state to offer evidence of public opinion polls, nor do we believe that the state must offer testimony from witnesses who claim to have been misled." 673 N.E.2d 1253, 1259 (Ohio 1996).

Evidence of instances of actual consumer confusion or deception is not required where "the language used is readily susceptible of interpretation by an objective observer without resort to proof from members of the public." Id.

Ohio's conclusion that production claims without a disclaimer are potentially misleading or confusing has the support of the FDA as well as a number of other states. The FDA guidance specifically states:

[E]ven such a statement, which asserts that rbST has not been used in the production of the subject milk, has the potential to be misunderstood by consumers. Without proper context, such statements could be misleading. Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading. . . . [A]ccompanying the statement "from cows not treated with rbST" with the statement that "No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows" would put the claim in proper context.

59 Fed. Reg. 6279. Alaska, Wisconsin, Illinois, and Pennsylvania have also issued standards requiring that the "no significant difference" language accompany production claims. See Alaska Stat. § 17.20.013; Wis. Admin. Code ATP § 83.02; Illinois Dep't of Public Health, Technical Information Bulletin/Dairy #2 (November 2, 2007); Pennsylvania Dep't of Agriculture, Milk Labeling Standards 2.0.1.17.08 (January 17, 2008).

This court finds that the Ohio rule, using the FDA guidance as a roadmap, strikes the right balance between preventing misleading information and providing enough information for consumers to make an informed choice. The Ohio rule appropriately prohibits misleading information by banning misleading

composition claims, and encourages dissemination of accurate non-misleading production claims. The rule accommodates the interests of processors who want to appeal to the organic market and consumers who want to avoid milk from cows treated with artificial hormones while at the same time protecting producers of milk from cows treated with artificial hormones from consumer confusion.

b. *Unduly Burdensome*

Plaintiffs argue that even if the disclaimer requirement is reasonably related to the State's interest in preventing deception of consumers, it still violates the First Amendment because it is unduly burdensome. Plaintiffs assert two grounds for their argument- first, that the cost of compliance with the Ohio rule renders it unduly burdensome, and second, that the formatting restrictions in the Ohio rule render it unduly burdensome, particularly on small containers. The court finds no merit in plaintiffs' first argument and concludes that it cannot decide the issues surrounding the second argument on summary judgment.

In support of their argument, plaintiffs have submitted affidavits from various processors that contain estimates of how much it would cost for each processor to change their labels. Ben & Jerry's, for example, estimates it could cost up to \$250,000 in order to comply with the Ohio rule. But the affidavit fails to demonstrate how this estimate relates to their total production costs or what percentage it is of their regular marketing budget. It is a matter of common knowledge that product labels are often

changed in the regular course of business. Plaintiffs have given this court no context by which it can decide whether the cost of compliance is an undue burden. Because plaintiffs have failed to produce any evidence from which it could conclude that the Ohio rule causes a financial burden so undue as to chill their right to make an accurate production claim, they have failed to raise a genuine issue of material fact on this issue.

Analysis of plaintiffs' second argument, that the Ohio rule's formatting requirements are unduly burdensome, is less straightforward. Plaintiffs argue that the rule is unduly burdensome because it requires the disclaimer language to be contiguous to and in exactly the same font, style, case, and color and at least half the size (but no smaller than seven point font) as the production claim. In response to plaintiffs' argument, the Director has submitted a number of labels from processors who have complied with the rule, demonstrating its ease of compliance. But plaintiffs claim this evidence is insufficient because it does not take into account the actual size of the container. According to plaintiff, in instances involving small containers, such as yogurt, it is impossible to comply with the Ohio rule.

In Ibanez, the Court found that where the disclaimer required so much detail that it effectively ruled out the protected speech entirely, it was unduly burdensome. Ibanez, 512 U.S. at 146-147. Here, if plaintiffs can demonstrate that the Ohio rule effectively rules out their ability to make an accurate production claim, then the rule would be unduly burdensome. However, based on the evidence submitted with the parties'

motions it is impossible for this court to determine whether or not the required disclosure can fit on a "small" dairy container or what particular label and design qualifies as "small." Because this court finds that it is not possible to determine, based on the submitted evidence, whether the disclaimer requirement is unduly burdensome due to its formatting requirements on "small" containers, summary judgment on this issue is denied to all parties.

C. Commerce Clause

Plaintiffs offer two theories of why the Ohio rule violates the dormant Commerce Clause of the U.S. Constitution. U.S. Const., Art. I, § 8, cl. 3. First, they argue that the rule is "per se" invalid as either a "direct" local regulation of interstate commerce or a discriminatory regulation. Second, they argue that under the balancing test of Pike v. Bruce Church, 397 U.S. 137, 142 (1970), the burdens that the Ohio rule imposes on interstate commerce "clearly exceed [its] putative local benefits." Neither theory is persuasive.

1. The "Direct Regulation" Theory

As recently noted by the Sixth Circuit "[w]hat counts as a 'direct' burden on interstate commerce has long been a matter of difficulty for courts, and, presumably due to its questionable value as an analytical device, the 'direct/incidental' distinction has fallen out of use in dormant commerce clause analysis." Tenn. Scrap Recyclers Ass'n v. Bredesen, 556 F.3d

442, ___, 2009 U.S. App. LEXIS 2744, at *9-10 (6th Cir. February 13, 2009) citing Ark. Elec. Coop. Corp. v. Ark. Pub. Serv. Comm'n, 461 U.S. 375, 390 (1983) ("[I]t is difficult to square the mechanical line . . . based on a supposedly precise division between 'direct' and 'indirect' effects on interstate commerce, with the general trend in our modern Commerce Clause jurisprudence to look in every case to 'the nature of the state regulation involved, the objective of the state, and the effect of the regulation upon the national interest in the commerce.'") (citations omitted). Thus, the Sixth Circuit has concluded that the direct regulation doctrine "appears to have been repudiated" and that Supreme Court precedent dictates analyzing the dormant Commerce Clause under two separate prongs. Tenn. Scrap Recyclers Ass'n, 2009 U.S. App. LEXIS 2744, at *10. First, if the law is protectionist, one that benefits in-state interests and burdens out-of-state interests, the law will be struck down. Id. at *12; Granholm v. Heald, 544 U.S. 460, 487 (2005). If, however, the Court determines that the law is not "protectionist," it should then apply the deferential Pike balancing test. Tenn. Scrap Recyclers Ass'n, 2009 U.S. App. LEXIS 2744, at *12.

2. Protectionist Purpose Theory

Plaintiffs have failed to show how the Ohio rule discriminates against out-of-state interests. In order to show that a law discriminates in practical effect, plaintiffs must show "both how local economic actors are favored by the legislation, and how out-of-state actors are burdened by the

legislation." Cherry Hill Vineyards, LLC v. Lilly, 553 F.3d 423, 432 (6th Cir. 2008) (quoting Eastern Ky. Resources v. Fiscal Court, 127 F.3d 532, 543 (6th Cir. 1997)).

Plaintiffs have failed to show how local economic actors are favored by the Ohio rule.¹² The Ohio rule is not discriminatory because it does not treat Ohio dairy producers more favorably than other dairy producers throughout the country. The plaintiffs argue that the rule is discriminatory because it imposes greater burdens on out-of-state national labels, but any Ohio producer who wants to make a non-use of rbST claim is equally affected by this law. All dairy producers, in Ohio and elsewhere, are subject to the Ohio labeling requirements and there is no evidence that such labeling requirements work to the benefit of Ohio dairy producers at the detriment of out-of-state dairy producers. Plaintiffs' argument is more akin to stating that the law discriminates against dairy producers that do not use rbST as opposed to dairy producers that do use rbST. But the Commerce Clause "protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations." Minn. v. Clover Leaf Creamery Co., 449 U.S. 456, 474 (1981). "The fact that the burden of a state regulation falls on some interstate companies does not, by itself, establish a claim of discrimination against interstate commerce." Exxon Corp. v. Governor of Maryland, 437 U.S. 117, 126 (1978).

¹²This fact distinguishes this case from Hunt v. Washington Apple Advertising Comm'n, 432 U.S. 333 (1977), where the Court found that the law, though neutral on its face, benefitted the state of North Carolina to the detriment of the state of Washington.

Plaintiffs argue that Ohio's protectionist intent can be determined from the fact that Ohio dairy producers were behind the enactment of the Ohio rule, citing comments from dairy farmers at a public hearing that they were in support of the rule. But the fact that some Ohio producers testified in favor of the Ohio rule does not render the rule protectionist when it is not protectionist in effect.

3. The "Undue Burden" Theory

Because the Ohio rule is not protectionist, it must be analyzed under the second prong of the modern test, the Pike balancing test. Tenn. Scrap Recyclers Ass'n, 2009 U.S. App. LEXIS 2744, at *12. Under the deferential Pike test, the court will uphold the Ohio rule unless the burden it imposes upon interstate commerce is "clearly excessive in relation to the putative local benefits." Pike, 397 U.S. at 142. "[T]he extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate commerce." Id.

a. Burden On Interstate Commerce

The Commerce Clause protects only interstate markets, not particular interstate firms, from prohibitive or burdensome regulations. Exxon Corp., 437 U.S. at 127-128; See also Tenn. Scrap Recyclers Ass'n, 2009 U.S. App. LEXIS 2744, at *15-17 (holding that a "tag and hold" ordinance was a local law with

local effect that imposed only a temporary burden on the shipment of scrap metal by Memphis dealers and as such, the law did not regulate the national scrap metal industry but only the small part of that industry that operated in Memphis). The Ohio rule's effect on the individual firms making up IDFA or OTA is relevant for commerce clause purposes only to the extent that it burdens the national market. See Tenn. Scrap Recyclers Ass'n, 2009 U.S. App. LEXIS 2744 at *16. "Absent a showing of harm to the national . . . market, the [plaintiffs'] dormant commerce clause claim must fail." Id. at *16-17. "Although evidence regarding a particular company may be suggestive, the benefit-to-burden calculation is based on the overall benefits and burdens that the statutory provision may create, not on the benefits and burdens with respect to a particular company or transaction." Quik Payday, Inc. v. Stork, 549 F.3d 1302, 1309 (10th Cir. 2008).

When discussing the applicable markets at issue in this case, IDFA's brief refers to "dairy products" while OTA's brief refers to "organic dairy products." Plaintiffs have failed to demonstrate that the Ohio rule places a burden on either market. Although IDFA says that its members produce over 85 percent of the milk, cultured products, cheese and frozen desserts produced in the United States, it has provided no evidence detailing what percentage of its membership wishes to label their products as produced without rbST. Nor has it provided any evidence that those processors would withdraw from the market given the restrictions of the Ohio rule. Similarly, OTA has not demonstrated what percentage of its membership, if any, would withdraw from the market when faced with compliance with the Ohio

rule.

Plaintiffs' evidence supporting their theory of undue burden consists of affidavits from some of their members analyzing the effect they believe the Ohio rule will have on their individual firms.¹³ Those affidavits state that due to distribution limitations, the processors are unable to re-label their products for Ohio only and thus, they are left with two choices: change all their labels nationally to comply with the Ohio rule or withdraw from the Ohio market altogether. But neither plaintiff presented evidence that, in fact, any of these processors would withdraw from the market rather than re-label their products.

To the extent the Ohio rule may be said to "force" dairy processors to create one label for all states, it is only because those processors will not modify their production and distribution systems to differentiate between Ohio bound and non-Ohio bound dairy products.¹⁴ See e.g. Nat'l Elec. Mfrs. Ass'n v.

¹³Although not properly authenticated evidence, IDFA submitted a power point entitled "rbGH Labeling" produced by the Ohio Ecological Food and Farm Association, which states that nationwide only 15.2 percent of dairy operations use rbGH. IDFA App. II p. 609-622. However, this document only purports to tell the court the number of dairy operations that use rbGH without stating how this translates to the number of dairy processors that want to label their products as coming from dairy cows not treated with rbGH or what percentage of these processors will withdraw from the market because of the Ohio rule.

¹⁴Plaintiffs have failed to raise a genuine dispute of fact regarding whether the cost of compliance to change their labels is an undue burden on commerce. Plaintiffs' have submitted cost estimates from individual firms ranging between \$27,000 for smaller processors to \$250,000 for the largest processors. But again, plaintiffs have produced no context for the court on how these numbers will impact the market, rather than individual firms, and no processor has indicated these costs to be so high they will withdraw from the market. The Ohio rule's effect on the

Sorrell, 272 F.3d 104, 110 (2d Cir. 2001). But the Court has rejected the notion that the Commerce Clause protects particular structure or methods of operation in the retail market. Exxon Corp., 437 U.S. at 127.

Even if some processors choose to withdraw from the market, that information would not be sufficient to raise a genuine issue of material fact without knowing how many would make this choice or how widespread the impact would be. See Exxon Corp., 437 U.S. at 127 (holding that even if some refiners stop selling in Maryland, that does not necessitate a finding that the statute impermissibly burdens interstate commerce). Plaintiffs have essentially provided the court with no evidence of the impact on the market, rather than on individual firms.

Plaintiffs' argue the Ohio rule has the "practical effect" of regulating conduct beyond Ohio's borders, citing Edgar v. Mite Corp., 457 U.S. 624 (1982), Healy v. Beer Inst., 491 U.S. 324 (1989) and Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573 (1986). But Brown-Forman and Healy involved price affirmation statutes that directly tied their labeling laws to products sold out of state and Edgar involved an Illinois law that regulated transactions which took place across state lines. Here, the Ohio rule only regulates labels on products sold in Ohio. The fact that the Ohio rule has some effect outside Ohio's borders is not determinative. "Every state police statute necessarily will affect interstate commerce in some degree, but

individual firms making up IDFA or OTA is relevant for commerce clause purposes only to the extent that it burdens the national market. See Tenn. Scrap Recyclers Ass'n, 2009 U.S. App. LEXIS 2744 at *16.

such a statute does not run counter to the grant of Congressional power merely because it incidentally or indirectly involves or burdens interstate commerce." Milk Control Bd. v. Eisenberg Farm Prods., 306 U.S. 346, 351 (1939). The Ohio rule does not regulate the national dairy market nor the national organic market, but simply regulates what labels can be used in Ohio.

Plaintiffs also argue that if Ohio can impose such a strict labeling rule, so could other states, thereby stifling interstate commerce. While it is true that other states have regulated labeling of dairy products that come from cows not treated with rbST, plaintiffs have not demonstrated that any of these other laws conflict with the Ohio rule. In fact, plaintiffs do not dispute Ohio's law is the strictest and that compliance with Ohio's labeling restrictions would keep them in compliance with the laws in other states. While plaintiffs argue that there is no guarantee Ohio law will be the strictest for long, this is nothing more than speculation. See Sorrell, 272 F.3d at 112 (holding there must be an actual conflict, rather than just a risk, between the challenged regulation and regulations in other states in order to violate the Commerce Clause). "The idea that there is a general interest in [regulatory] uniformity is inconsistent with our [society's] decision to have separate states with separate legislative competencies, including separate competencies to regulate commerce." Id. at 113 quoting Donald H. Regan, Siamese Essays: (I) CTS Corp. v. Dynamics Corp. of America and Dormant Commerce Doctrine; (II) Extraterritorial State Legislation, 85 Mich. L. Rev. 1865, 1883 (1987).

b. *The Putative Local Benefits of the Ohio Rule*

As discussed in more detail in the First Amendment portion of this opinion, the Ohio rule has an important local benefit—preventing the dissemination of misleading labeling on dairy products. The Court has recognized that the States have always possessed a legitimate interest in “‘the protection of . . . [their] people against fraud and deception in the sale of food products’ at retail markets within their borders.” Florida Lime & Avocado Growers, 373 U.S. at 144 (quoting Plumley v. Massachusetts, 155 U.S. 461, 472 (1894)).

c. *Balancing of the Pike Factors*

Because this court finds that plaintiffs have failed to show that the Ohio rule burdens interstate commerce and because it is a valuable tool to prevent dissemination of misleading information,¹⁵ the burden it imposes on interstate commerce is not “clearly excessive in relation to its putative local benefits.” Pike, 397 U.S. at 142.¹⁶ Accordingly, this court

¹⁵In Lever Bros. Co. v. Maurer, 712 F. Supp. 645 (S.D. Ohio 1989), this court was confronted with an Ohio law that precluded the use of the word “butter” in labeling or advertising any product made to imitate or substitute for butter. In Lever Brothers, the statute prevented consumers from knowing that butter was in plaintiffs’ butter product. This court held there is nothing inherently misleading about the use of the word “butter.” Thus, Lever Brothers is clearly distinguishable from the instant case.

¹⁶The extent of the burden that will be tolerated will of course depend whether a rule can be promoted as well with a lesser impact on interstate activities. Minn. v. Clover Leaf Creamery Co., 449 U.S. 456, 471 (1981). Because plaintiffs have

grants summary judgment to the Director on plaintiffs' Commerce Clause claims.

D. Preemption

OTA asserts that the Ohio rule is preempted by the Organic Foods Production Act (OFPA), 7 U.S.C. § 6501 et seq., and attendant National Organic Program regulations (NOP), 7 C.F.R. § 205 et seq. OTA argues that the OFPA occupies the field of organic labeling or alternatively that the Ohio rule stands as an obstacle to the purposes of the OFPA. The court finds neither argument persuasive.

The OFPA and NOP establish national standards for production and handling of foods labeled "organic." The OFPA sets forth its purposes, which are:

(1) to establish national standards governing the marketing of certain agricultural products as organically produced products; (2) to assure consumers that organically produced products meet a consistent standard; and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

7 U.S.C. § 6501. The OFPA prohibits a person from selling or labeling an agricultural product as "organically produced" unless the product was produced and handled in accordance with the Act.

7 U.S.C. § 6505.

The OFPA authorizes the Secretary of Agriculture to promulgate regulations to carry out the OFPA and to establish a National List of approved and prohibited substances for use in

failed to show any impact the Ohio rule has on interstate commerce, this court cannot determine whether a different rule would have a lesser impact.

products to be sold or labeled as "organically produced." 7 U.S.C. § 6521; 7 U.S.C. § 6517. Recombinant DNA technology, such as rbST, is not permitted to be used in organic dairy. 7 C.F.R. § 205.2 (listing recombinant DNA technology as an excluded method); 7 C.F.R. 205.105(e). Subpart D of the NOP specifically regulates labels, labeling and marketing information for use of the term "organic" on labels. 7 C.F.R. §§ 205.300-205.311.

The OFPA allows states to create a plan for the establishment of a State organic program only if the plan is submitted to and approved by the Secretary of Agriculture. 7 U.S.C. § 6507. Such a plan may contain more restrictive requirements governing the organic certification of farms and handling operations and the production and handling of agricultural products that are to be sold or labeled as organically produced and must further the purposes of the Act, not be inconsistent with the Act, and not be discriminatory towards agricultural commodities organically produced in other States. 7 U.S.C. § 6507; See also 7 C.F.R. § 205.620.

The Supreme Court has held that under Article VI of the United States Constitution state laws that conflict with federal laws are without effect. Altria Group, Inc. v. Good, __ U.S. __, 129 S. Ct. 538, 543 (2008). Absent express preemption in the statute, the Supreme Court has recognized two other types of preemption: "field pre-emption, where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, and conflict pre-emption, where compliance with both federal and state regulations is a physical impossibility or where state law

stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Gade v. National Solid Wastes Management Ass'n, 505 U.S. 88, 98 (1992)(citations omitted). When addressing questions of preemption, the analysis begins with the assumption that "the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Altria Group, Inc., 129 S. Ct. at 543 quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). "That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States." Altria Group, Inc., 129 S. Ct. at 543.

1. Field Preemption

Where a law is so "pervasive that there is a reasonable inference that Congress left no room for the States to supplement it" that law will preempt the entire field. Gade, 505 U.S. at 98. The Court will look to the purpose of Congress in the legislative history and text of the statute to determine if Congress intended a comprehensive congressional design. See Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 147-148 (1963).

OTA argues the OFPA preempts the field of organic labeling and prevents Ohio and other states from unilaterally imposing labeling requirements on organic dairy operations because the OFPA provides a comprehensive statutory and regulatory scheme that governs the production, distribution, and marketing of organic food products and is made up of over 20 statutes and over 600 regulations.

While it is true that the OFPA's purpose is to "establish national standards governing the marketing of certain agricultural products as organically produced products" and to have a "consistent standard" (7 U.S.C. § 6501), this purpose only illustrates Congress's intent to regulate the field of marketing products that hold themselves out to be "organic," not to regulate the field of organic products that have misleading information on their labels. The Ohio rule does not govern the labeling or marketing of organic products, but governs all dairy products that make misleading claims on their labels. The purpose of the OFPA is to ensure that organic foods are properly labeled as organic and does not govern the contents of the entire label.

In Gade, the Court analyzed whether or not an Illinois statute was preempted by the Occupational Safety and Health Act (OSH Act). 505 U.S. at 107. The Court held that only those regulations that directly, substantially, and specifically regulated occupational safety and health were occupational safety and health standards within the meaning of the Act. Id. In its discussion, the Court stated that while some safety laws of general applicability may have a "direct and substantial" effect on worker safety, they could not fairly be characterized as "occupational" and therefore preempted by OSHA because they regulated workers simply as members of the general public. Gade, 505 U.S. at 107. Here, the Ohio rule is more like a law of general applicability, that just happens to have an effect on organic products in addition to other types of dairy products. Not all dairy products that do not contain artificial hormones

are organic. The Ohio rule does not change the way a product is certified or labeled as being organic. It only affects the label on an organic product if it is a dairy label that contains misleading information regarding artificial hormones or other misleading information.

Here, OFPA points this court to legislative history from the Act that "organic certification standards should be national in scope, tough and fully enforced" (135 Cong. Rec. 29411 (1989)) and "the organic industry is encouraged to inform consumers about all material used in organic production" (S. Rep. No. 101-357, at 300 (1990)).¹⁷ However, this only establishes a legislative intent that certification of organic products be national, a purpose not related to whether or not a dairy label that happens to be for an organic product will be permitted to contain misleading information. Moreover, the Ohio rule does not prevent organic producers from informing consumers about the materials

¹⁷By unopposed motion, OTA has moved this court to take judicial notice of the Congressional Record and Senate Report of the 101st Congress, 2d session, which contains some of the legislative history of the OFPA and the document titled "Organic Dairy and the Role of Pasture" by the Natural Marketing Institute, commissioned by the United States Department of Agriculture. Judicial notice, under Fed. R. Evid. 201, may be taken when a fact is not subject to reasonable dispute in that it is either generally known within the territorial jurisdiction of the trial court or capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. Excerpts from the legislative history of the OFPA are facts that are not subject to reasonable dispute and thus, judicial notice of the legislative history of the OFPA is granted. However, the findings by the Natural Marketing Institute are not facts which are either "generally known" or "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned" and therefore, judicial notice of this document is denied.

used in organic production. Rather, the Ohio rule specifically permits production claims as long as they are not misleading.

The Court has recognized that the States have always possessed a legitimate interest in “‘the protection of . . . [their] people against fraud and deception in the sale of food products’ at retail markets within their borders.” Florida Lime & Avocado Growers, 373 U.S. at 144 (quoting Plumley v. Massachusetts, 155 U.S. 461, 472 (1894)). While OFPA prohibits the use of certain hormones and chemicals in organic production, OTA does not cite anything in the OFPA or its regulations demonstrating that there is no room for states to exercise their traditional police powers to regulate false and misleading labeling when referring to these hormones or chemicals. Thus, this court finds that the OFPA did not preempt the field of labeling on all organic products.

2. Conflict Preemption

OTA also argues that the Ohio rule “stands as an obstacle” to the full implementation of the OFPA. In order to be an obstacle to a federal law, it is not enough that the goal of both federal and state law are the same. Rather a state law is preempted “if it interferes with the methods by which the federal statute was designed to reach that goal.” Gade, 505 U.S. at 103.

As previously noted, the OFPA’s purpose was to establish national standards governing the marketing of organically produced products, to assure consumers that organically produced products meet a consistent standard, and to facilitate interstate commerce in organically produced food. 7 U.S.C. § 6501. But the

Ohio rule does not stand as an obstacle to these purposes. The Ohio rule does not hinder the national marketing of products labeled "organic," does not change the consistent standard of organic products established by the OFPA, and does not interfere with interstate commerce of organic products.

Citing Gade, OTA argues that because the OFPA contains a provision for a Secretary-approved state plan, then the Ohio rule is impliedly preempted. In Gade, the Court found that the state of Illinois' interim occupational safety and health regulations were preempted by the OSH Act because those regulations were promulgated without receiving the approval of the Secretary of Labor for a state plan as required by the OSH Act. The Court found it significant that the OSH Act specifically required the state to submit a plan if it wished to "assume responsibility" for the "development and enforcement . . . of occupational safety and health standards relating to any occupational safety or health issue with respect to which a Federal Standard has been promulgated." Id. at 99. The Court held that such a provision implied that the state first had to get approval for a state plan before regulating the occupational health and safety within the state. Id. at 103. Because the state regulation at issue was not approved and had the purpose of regulating occupational safety and health, that state law was preempted. "To allow a State selectively to 'supplement' certain federal regulations with ostensibly nonconflicting standards would be inconsistent with this federal scheme of establishing uniform federal standards, on the one hand, and encouraging States to assume full responsibility for development and enforcement of their own OSH

programs, on the other." Id.

OTA argues that the OFPA preempts the Ohio rule because, as in Gade, states are only allowed to regulate organic production to the extent that such a regulatory plan is approved by the Secretary of Agriculture in accordance with the provisions of the Act. 7 U.S.C. § 6507. Only then can the states impose requirements that are more restrictive than the Act. 7 U.S.C. § 6507. But Ohio is not required under the OFPA to obtain approval of the Ohio rule because the rule regulates false or misleading dairy labeling and does not regulate organic production or labeling products as "organic." Thus, the situation here is different from that in Gade because Ohio is not attempting to regulate an area for which the OFPA specifically requires an approved state plan.

OTA argues the Ohio rule is an obstacle to the purposes of the OFPA because it prevents organic food processors from notifying consumers that the processors are in compliance with organic regulations, such as the prohibition on the use of antibiotics, synthetic hormones, and pesticides. But the Ohio rule specifically makes exception for accurate production claims and does not prevent OTA's members from communicating their message to consumers. Nothing in the Ohio rule would prevent a producer from labeling the product as "organic."

Thus, the Ohio rule is not preempted by the OFPA under either the theory of field preemption or obstacle preemption and the Director's motion for summary judgment is granted on OTA's

preemption claim.¹⁸

E. Vagueness

OTA has argued that the Ohio rule is void for vagueness because its use of the word “may” necessarily gives the Director the ability to enforce the statute in a discriminatory and arbitrary manner. The court disagrees.

Because the Ohio rule has yet to be enforced in any manner, OTA is essentially bringing a facial challenge to the regulation on vagueness grounds. A plaintiff is permitted to make a facial challenge to a law on vagueness grounds when that law implicates plaintiff’s First Amendment rights. See Belle Maer Harbor v. Charter Twp. of Harrison, 170 F.3d 553, 557 (6th Cir. 1999). Here, plaintiff challenges the use of the word “may” in sections (B) and (D) of the Ohio rule. Although this court ultimately concludes that in large part section (B) of the Ohio rule does not violate plaintiffs’ First Amendment rights, it still implicates those rights because it requires plaintiffs to speak when they rather would not. Section (D), on the other hand, does not implicate plaintiffs’ First Amendment rights because section (D) prohibits composition claims that are inherently misleading and as such that speech is not entitled to any First Amendment protection whatsoever. Cent. Hudson Gas & Elec. Corp., 447 U.S. at 566 (holding that in order for commercial speech to be protected by the First Amendment it must at least concern lawful

¹⁸IDFA argued that if the Ohio rule was preempted, it was not severable and the entire Ohio rule failed. Because this court finds the Ohio rule was not preempted, it need not reach IDFA’s argument regarding severability.

activity and not be misleading). Because Section (D) does not even implicate plaintiffs' First Amendment rights, OTA cannot bring a facial challenge to that section of the rule and this court will only consider OTA's facial attack on section (B) of the regulations.

An ordinance is void-for-vagueness under the Due Process Clauses of the Fifth and Fourteenth Amendments if it fails, (1) to define the offense with sufficient definiteness that ordinary people can understand prohibited conduct, and (2) to establish standards to permit law enforcement to enforce the law in a non-arbitrary, non-discriminatory manner. See Kolender v. Lawson, 461 U.S. 352, 357 (1983). Where a statute reaches expression sheltered by the First Amendment, the doctrine demands a greater degree of specificity than in other contexts. See Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498-99 (1982); Belle Maer Harbor, 170 F.3d at 559 (6th Cir. 1999). However, courts do not require "mathematical certainty" from the language of a statute (Grayned v. City of Rockford, 408 U.S. 104, 110 (1972)) and perfect clarity and precise guidance has never been required (United States v. Williams, __ U.S. __, 128 S. Ct. 1830, 1845 (2008)).

"A vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application." Grayned, 408 U.S. at 108-109 (1972). Where statutory language imposes a "standardless sweep" that allows "policemen, prosecutors, and juries to pursue their personal predilections" the law will be considered impermissibly

vague. See Smith v. Goguen, 415 U.S. 566, 575 (1974).

"Legislatures may not so abdicate their responsibilities for setting the standards of the criminal law." See Smith, 415 U.S. at 575.

OTA argues that Section (B) of the Ohio rule is unconstitutionally vague because of its use of the word "may." The rule states: "a dairy label which contains a production claim that 'this milk is from cows not supplemented with rbST' (or a substantially equivalent claim) *may* be considered misleading on the basis of such language" if the verification requirements are not satisfied and the disclaimer language not used. Ohio Admin. Code 901:11-8-01(B)(emphasis added). OTA argues that the use of "may" gives the Director unfettered discretion to enforce the rule in an arbitrary manner and therefore violates the vagueness doctrine.

The Court finds that section (B) of the Ohio rule is not vague. It states that production claims may be misleading, but then creates a safe harbor, giving processors clear guidance on what they can do to avoid violating the rule. The rule specifically states that a production claim may be misleading "unless" the processor satisfies the verification requirements and includes a proper disclaimer on the label. Thus, Section (B) provides notice of the standards to which processors must conform when they wish to make a production claim on their labels. At the same time, it establishes a guideline to govern enforcement of the law. The Court has recognized that there are some "areas of human conduct where, by the nature of the problems presented, legislatures simply cannot establish standards with great

precision." Smith, 415 U.S. at 581. Obviously, here, the Ohio rule could not provide an example of every semantic construction rendering a label misleading. If it attempted to do so, the regulation would run on indefinitely. Instead, they have provided a clear instruction as to what is *not* misleading.

OTA argues in this context whether or not a statement "may be misleading" refers to whether the Director finds the statement misleading. In fact, the term "may be misleading" refers to whether or not consumers will find the statement misleading. Obviously, not everyone will find the statement misleading, particularly depending on their knowledge of the scientific data behind rbST. But because it is likely many people will be misled, the Director has promulgated a rule to protect those consumers.

Thus, the use of the term "may" in the statute does not impose a "standardless sweep" that allows arbitrary enforcement, but rather seeks to give additional guidance when a dairy processor seeks to make a production claim about rbST. It specifically defines what is *not* misleading. Thus, the Director's motion for summary judgment is granted as to the OTA's claims of vagueness.

IV. Conclusion

For the reasons set forth above, plaintiffs' motions for summary judgment are DENIED (Doc. 21 in case 2:08-cv-628, Doc. 18 in case 2:08-cv-629) and the Director's motion for summary judgment is GRANTED in part and DENIED in part (Doc. 36 in case 2:08-cv-628, Doc. 25 in case 2:08-cv-629). The plaintiffs have not shown a strong likelihood of success on the merits such that granting a preliminary injunction would be appropriate and the

court therefore DENIES both plaintiffs' motions for preliminary injunction (Doc. 5 in case 2:08-cv-628, Doc. 5 in case 2:08-cv-629).

It is so ORDERED.

s/ James L. Graham

JAMES L. GRAHAM
United States District Judge

DATE: April 2, 2009